

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 20 APR 2006

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Applicant's or agent's file reference P1126PC10	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/US05/04630	International filing date (day/month/year) 14 February 2005 (14.02.2005)	Priority date (day/month/year) 14 February 2004 (14.02.2004)	
International Patent Classification (IPC) or national classification and IPC IPC: C07D 471/04( 2006.01);487/04( 2006.01);A61K 31/519( 2006.01) USPC: 544/279,280;514/264.1,264.11,265.1			
Applicant IRM LLC			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 13 September 2005 (13.09.2005)		Date of completion of this report 27 March 2006 (27.03.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Thomas C. McKenzie, Ph.D. Telephone No. (703) 272-1600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/04630

**Box No. I Basis of the report**1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:  
pages 1-55 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:  
pages 56-61 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☐ the drawings:  
pages NONE as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

*\* If item 4 applies, some or all of those sheets may be marked "superseded."*

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US05/04630**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)	Claims <u>6 and 9</u>	YES
	Claims <u>1-5, 7, 8, and 10</u>	NO
Inventive Step (IS)	Claims <u>6 and 9</u>	YES
	Claims <u>1-5, 7, 8, and 10</u>	NO
Industrial Applicability (IA)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO

## 2. Citations and Explanations (Rule 70.7)

Claims 1, 2, 4, and 5 lack novelty under PCT Article 33(2) as being anticipated by YAKHONTOV (Khimiya Geterotsiklicheskikh Soedinenii). The compound VI fits formula Ib with R1 = R2 = phenyl, X = N, R4 = ethyl, and n = 0.

Claims 1, 2, 4, and 5 lack an inventive step under PCT Article 33(3) as being obvious over YAKHONTOV (Khimiya Geterotsiklicheskikh Soedinenii). For reasons cited above.

Claims 1-5, 7, 8, and 10 lack novelty under PCT Article 33(2) as being anticipated by SU 194829 (Ordzhonikidze). The compound with RN 19144-66-2 fits formula Ib with R1 = R2 = phenyl, X = N, R4 = H, and n = 0.

Claims 1-5, 7, 8, and 10 lack an inventive step under PCT Article 33(3) as being obvious over SU 194829 (Ordzhonikidze). For reasons cited above.

Claims 6 and 9 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the compound or use of these claims.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-5 and 7-10 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims 7-10 are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: Applicants lack enablement for making any hydrates, solvates, isomers, or prodrugs. Preparing all these derivatives is an unpredictable art.

Claims 7-10 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims 7-10 are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: inhibitors of the Bcr-abl, Flt-3, Alk, and b-Raf enzymes have no art-recognized therapeutic use.